UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

APRIL L. HILL,

Plaintiff,

Case No. 19-CV-12198
HON. GEORGE CARAM STEEH

v.

BAYER CORPORATION, et al.,

Defendants.
_____/

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS [ECF No. 12] AND GRANTING DEFENDANTS' SECOND REQUEST FOR JUDICIAL NOTICE [ECF No. 27]

I. Overview

Plaintiff April Hill brought this products liability suit arising out of injuries allegedly caused by an Essure permanent birth control device manufactured by Defendants. Plaintiff has sued Defendants Bayer Corp., Bayer Healthcare, LLC, and Bayer Healthcare Pharmaceuticals Inc. (collectively "Bayer"). Now before the court is Defendants' motion to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) on the grounds that Plaintiff's claims are preempted or fail to state plausible claims. Oral argument was held, and the parties were permitted to file supplemental briefs. Defendants filed a second request for the court to take judicial notice of Patient Information Booklet (2009). For the

reasons set forth below, Defendants' motion to dismiss shall be GRANTED such that all of Plaintiff's claims are DISMISSED. Defendants' second request for judicial notice is also GRANTED.

II. Factual Background

The recitation of the facts below comes from the allegations of the Amended Complaint or from those documents that the parties agreed may be judicially noticed by the court. (ECF No. 4). Essure is a permanent female birth control device that is intended to cause a blockage of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth. *Id.* at PageID.99, ¶ 15. The micro-inserts are comprised of two metal coils which are inserted using hysteroscopic (camera) guidance. *Id.* at PageID.105, ¶ 33. Plaintiff alleges the device migrates from the fallopian tubes and perforates organs. *Id.* at PageID.99, ¶ 15. The device is inserted as part of a "non-surgical" outpatient procedure to be done without anesthesia. *Id.* at PageID.106, ¶ 41.

Essure had Conditional Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). *Id.* at PageID.99, ¶ 17; ECF No. 13-1. As a Class III medical device, Essure required premarket approval ("PMA") by the FDA. *Id.* at PageID.107, ¶ 48. Class III devices receive the most

federal oversight. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). Bayer discontinued sales of Essure after December 31, 2018. The FDA reviews a device's proposed labeling, which includes the Instructions for Use ("IFU") (for physicians) and Patient Information Booklet ("PIB") (for patients), as part of the premarket approval process. It "evaluates safety and effectiveness under the conditions of use set forth on the label," and "must determine that the proposed labeling is neither false nor misleading" before granting approval. *Id.* at 318 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). FDA may also specify requirements that apply to the training of practitioners who use the device, and these requirements must appear in the FDA-approved labeling. 21 U.S.C. § 360j(e). Once a device has been approved, a manufacturer cannot make changes to the labeling without FDA permission under "largely the same criteria" as the initial application. *Riegel*, 552 U.S. at 319.

Plaintiff was implanted with the Essure device on or around December 21, 2011. (Amended Complaint, ¶ 97). Plaintiff alleges that as a result of the implantation of Essure she has suffered abdominal pain, depression, fatigue, heavy bleeding, pain during intercourse, weight fluctuations, severe back pain, migraines, urgent and frequent urination, heart palpitations, loss of libido, bowel issues, pelvic pain, and hot flashes.

(ECF No. 4, PageID.127-28, ¶ 98). She further alleges that the device has potentially migrated and embedded in areas outside of her fallopian tubes which she alleges will require her to have a hysterectomy. (ECF No. 4, PageID.128, ¶ 98).

Plaintiff's Amended Complaint alleges five counts: (I) negligent training, (II) negligent risk management, (III) breach of express warranty, (IV) negligent misrepresentation, and (V) negligent failure to warn. Defendants argue that Plaintiff's claims are preempted and inadequately pled.

III. Standard of Law

Rule 12(b)(6) allows the Court to make an assessment as to whether the plaintiff has stated a claim upon which relief may be granted. Under the Supreme Court's articulation of the Rule 12(b)(6) standard in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 554-56 (2007), the court must construe the complaint in favor of the plaintiff, accept the allegations of the complaint as true, and determine whether plaintiff's factual allegations present plausible claims. "'[N]aked assertions' devoid of 'further factual enhancement'" are insufficient to "'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 557, 570). To survive a Rule 12(b)(6) motion to dismiss,

plaintiff's pleading for relief must provide "'more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.'" *D'Ambrosio v. Marino*, 747 F.3d 378, 383 (6th Cir. 2014) (quoting *Twombly*, 550 U.S. at 555). Even though the complaint need not contain "detailed" factual allegations, its "'factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the allegations in the complaint are true.'" *New Albany Tractor, Inc. v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir. 2011) (quoting *Twombly*, 550 U.S. at 555).

IV. Analysis

A. Judicial Notice

Defendants request that the Court take judicial notice of the 2009 Patient Information Booklet, approved by FDA in 2009 and in force at the time that Plaintiff received Essure. Federal Rule of Evidence 201(b) authorizes the Court to take judicial notice of facts that are "not subject to reasonable dispute" because they "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." The 2009 Patient Information Booklet is a publicly available federal agency document related to FDA premarket approval and the Court grants Defendants' request and takes judicial notice thereof. *See, e.g., Int'l Bhd. of Teamsters v. Zantop Air Transp. Corp.*, 394 F.2d 36, 40 (6th Cir.

1968) ("[A] Court may take judicial notice of the rules, regulations and orders of administrative agencies issued pursuant to their delegated authority.")

B. Preemption under the FDCA

The FDCA includes an express preemption clause that provides, in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court addressed the meaning of § 360k(a) in *Riegel*, *supra,* which involved a Class III medical device that had received premarket approval. The Court explained that to the extent that a state common-law duty imposes requirements "different from, or in addition to" the requirements imposed by the FDCA, those state common-law duties are expressly preempted by § 360k(a). *Id.* To escape preemption by § 360k(a), then, a state-law claim must be premised on the breach of a state-law duty that is the same as a duty imposed under the FDCA (or one

of its implementing regulations). *Id.* at 330 ("Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."). Put another way, the conduct that is alleged to give the plaintiff a right to recover under state law must be conduct that is forbidden by the FDCA. Thus, to determine whether Hill's claims are preempted, it is first necessary to identify precisely what conduct by Bayer is alleged to give rise to a claim under Michigan law. If that conduct is not prohibited by the FDCA, then Hill's claim, if successful, would have the effect of imposing on Bayer a requirement that is different from or in addition to the requirements imposed by the FDCA—and, for that reason, Hill's claim would be expressly preempted by § 360k(a).

If the conduct *is* prohibited by the FDCA, then a state-law claim premised on that conduct is not expressly preempted by § 360k(a). But that is not the end of the inquiry, for even if a claim is not *expressly* preempted by § 360k(a), it may be *impliedly* preempted under *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001). In *Buckman,* the Supreme Court held that, because enforcing the FDCA is exclusively the province of the federal government, there is no private right of action under the FDCA. *Id.* at 349 n. 4 ("The FDCA leaves no doubt that it is the Federal

Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.' 21 U.S.C. § 337(a).'"). Thus, a private litigant cannot sue a defendant for violating the FDCA. Similarly, a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist. *Id.* at 352–53. Instead, to avoid being impliedly preempted under *Buckman,* a claim must "rely[ ] on traditional state tort law which had predated the federal enactments in question[ ]." *Id*. at 353. In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*. *Id.* at 349 n. 4.

In sum, *Riegel* and *Buckman* create a "narrow gap" through which a plaintiff's state-law claim must fit if it is to escape express or implied

preemption. *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). "The plaintiff must be suing for conduct that *violates* the FDCA (or else his [or her] claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.

C. Negligent Training

Defendants argue that Plaintiff's negligent training claim pled in Count I should be dismissed because it is preempted by federal law, and lacks sufficient factual allegations to be plausible on its face but is merely boilerplate. Defendants complain Plaintiff has not alleged facts supporting a plausible inference that her own doctor was negligently trained in violation of federal standards, her doctor erred in placing her device, or her alleged injuries were causally linked to physician error arising from inadequate training. Defendants fault Plaintiff for not even identifying her own doctor.

To survive a preemption challenge, Plaintiff's negligent training claim must depend on allegations that Bayer breached FDA-approved training

obligations. Under federal law, when FDA specifies training requirements for Class III medical devices, those requirements must appear in the device's approved labeling. 21 U.S.C. § 360j(e). Essure's labeling provides:

> Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use and Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement until competence is established, typically 5 cases.

2013 IFU at 1 (ECF No. 13-7, PageID.404). Plaintiff's Amended Complaint alleges violations of those requirements. (ECF No. 4, PageID 144, ¶ 155). Specifically, the Amended Complaint alleges that Bayer breached FDA approved guidelines by (1) not ensuring that the implanting physicians completed the requirement preceptoring in Essure placement until competency, (2) not ensuring that the implanting physicians had read and understood the Physician Training Manual, and (3) not ensuring that the implanting physicians had "successful completion of Essure Simulator Training." *Id.* Because Plaintiff's negligent training claim is based on breach of FDA training requirements, Plaintiff's claim is not preempted by federal law. Unlike *DeLaPaz v. Bayer Healthcare, LLC.,* 159 F. Supp. 3d 1085, 1096 (N.D. Cal. 2016), relied upon by Bayer, this case involves

allegations that Bayer deviated from the FDA approved training. However, to the extent the claim is premised on training that is outside Essure's FDA training guidelines, such as the alleged failure to train physicians on how to use "specialized hysteroscopic equipment manufactured by a third party," (ECF No. 4, PageID.123, ¶ 80), or the alleged failure to train physicians on "how to remove Essure should it fail," (ECF No. 4, PageID.124, ¶ 83), her negligent training claim as to those alleged deficiencies are preempted.

Bayer also faults Plaintiff for not pleading facts to show a causal link between her alleged injury and the alleged failure to train her implanting physician and argues her negligent training claim is mere boilerplate. Plaintiff alleges generally that the alleged failure to train caused the implanting physician's technique to cause the coils to migrate, perforate, fracture or cause other injury. (ECF No. 4, PageId.144-45, ¶ 156). But Plaintiff has not even identified her own doctor let alone pled facts suggesting a viable failure to train claim. It is not enough to set forth a "formulaic recitation of the elements of a cause of action," *D'Ambrosio*, 747 F.3d at 383. Plaintiff's failure to plead plausible facts in support of her failure to train claim is fatal, and having failed to satisfy the dictates of *Iqbal* and *Twombly,* that claim (Count I) shall be dismissed. *See McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 817-18 (E.D. Pa. 2016) (dismissing

negligent training claim for failure to plead facts suggesting a causal link between allegedly deficient training and injury).

D. Negligent Risk Management (Count II) and Negligent Failure to Warn (Count V)

Count II alleges negligent "risk management" and Count V alleges negligent "failure-to-warn." The two claims parallel each other as both are premised on Bayer's alleged failure to comply with federal reporting and other regulatory conditions. Thus, the court analyzes them together. In Count V of her Amended Complaint, Hill alleges that Bayer is liable for negligent failure-to-warn for failing to make disclosures to herself, her implanting physician, and the FDA. Despite the heading "negligent failure-to-warn," the Amended Complaint cites to a lengthy list of alleged federal regulatory violations, the vast majority of which do not involve warning requirements at all, but rather involve the alleged failure to make certain reports including adverse events to the FDA, and various other alleged violations as required by FDA regulations for the Conditional Premarket Approval ("CPMA"). (Amended Complaint, ¶¶ 199(a)-(z)). For the reasons discussed below, these claims shall be dismissed as preempted as supported by decisions of the Sixth, Eighth and Eleventh Circuits.[1]

[1]As discussed later in this opinion, the Fifth and Ninth Circuits have reached the opposite conclusion.

Hill seeks to hold Bayer liable for failure to warn her personally, her physician, and the FDA of adverse events. The FDA requires that all manufacturers or importers of medical devices "shall report[ ] whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices...may have caused or contributed to a death or serious injury." 21 U.S.C. § 360i(a)(1). The law is well established that there is no parallel federal requirement that Bayer had a duty to warn the general public or the medical community, and thus, those claims are expressly preempted because they are "different from, or in addition to," the Medical Device Amendments ("MDA") requirements. *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010); s*ee also Cupek v. Medtronics,* 405 F.3d 421 (6th Cir. 2005) (holding that any state law claim alleging failure to warn patients beyond warnings required by the FDA constitutes different or additional requirements under the pre-market approval ("PMA") process and thus not parallel); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000) ("to the extent that plaintiff's claim is premised on the adequacy of the warnings reviewed and approved by the FDA, . . . the claim is . . . preempted"). But the issue of whether Bayer can be held liable for its alleged failure to report adverse events to the FDA

under state law negligence principles presents a closer question. Hill argues that Bayer is liable for failing to report adverse events to the FDA which she claims is a state law cause of action known as "negligent risk management" or "negligent failure-to-warn." Hill relies solely on alleged violations of federal regulations under the FDCA.

The Sixth Circuit has not addressed the narrow issue presented here, and courts are divided on the issue. But the Sixth Circuit's decisions in *Kemp*, *supra,* and *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005) suggest that the Court of Appeals would not recognize a state law failure-to-warn tort claim for a medical device manufacturer's alleged failure to report adverse events to the FDA. In *Kemp*, the Sixth Circuit held that plaintiff's claim for fraud-on-the-FDA arising out of an allegedly defective pacemaker was preempted because permitting "a fraud claim premised on false representations to the FDA during the PMA process would conflict with well-established precedent that no implied private right of action exists under the FDCA." 231 F.3d at 236 And in *Cupek*, which involved allegedly defective pacemaker leads, the Sixth Circuit found that state law failure-to-warn claims are expressly preempted because those failure-to-warn claims would require defendant to comply with state requirements "different from" or "in addition to" federal requirements. 405 F.3d at 424. The Sixth Circuit

observed that it "is the Federal Government, not private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Id.* And the Sixth Circuit also stressed that a state law tort claim that is "a disguised fraud on the FDA" claim is preempted under *Buckman*. *Id.* That is exactly what Hill seeks to do here: to hold Bayer liable for alleged misrepresentations and withholding of information to the FDA. As observed in *Cupek*, it is for the federal government to prosecute suits for noncompliance with the MDA.

Although *Kemp* and *Cupek* support the conclusion that Hill's failure-to-warn claim premised on Bayer's alleged failure to report adverse events to the FDA are preempted under *Buckman*, because they did not squarely address the issue, the court discusses below the arguments of counsel and the relevant decisions that have done so.

Bayer argues that under the Supreme Court's holding in *Buckman*, a claimed violation of the FDCA, enforceable only by the government under 21 U.S.C. § 337(a), is subject to preemption. Bayer faults Hill for failing to point to any state analog which would require Bayer to report adverse events to the FDA. Bayer relies on *White v. Medtronic, Inc.*, No. 18-11590, 2019 WL 1339613, at *6 (E.D. Mich. Feb. 20, 2019) (Whalen, M.J.) (collecting cases), *report and recommendation adopted*, 2019 WL 1330923

(E.D. Mich. Mar. 25, 2019) (Cleland, J.), where the court held that the "federal requirement that manufacturers report adverse events to the FDA has no state law analog, and thus there is no parallel state cause of action." Bayer also relies on decisions from the Eighth and Eleventh Circuits holding that the claim that a manufacturer is liable for failing to report adverse events to the FDA is preempted because it is like the "fraud-on-the FDA" claim the Supreme Court held was impliedly preempted in *Buckman,* and that theory of liability "is not one that state tort law has traditionally occupied." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017); *see also In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liability*, 623 F.3d 1200, 1205-06 (8th Cir. 2010) (claims that manufacturer of medical device failed to provide FDA with adverse reports as required by federal regulations "are simply an attempt by private parties to enforce the MDA, claims foreclosed by § 337(a) as construed in *Buckman*, 531 U.S. at 349.").

Hill, on the other hand, relies solely on *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016). Indeed, the district court in that case faced with the identical issue presented here did find that Plaintiff's failure to warn claim premised on Bayer's alleged failure to report adverse events to the FDA was not preempted. The court relied on an *en banc*

decision of the Ninth Circuit reaching the same conclusion in a similar case and holding that a failure to warn premised on a medical device manufacturer's failure to report complaints about the device to the FDA was not preempted. *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc). In *Stengel*, the Ninth Circuit found that Arizona provided a parallel cause of action because it recognized a claim "for negligent failure to warn, and expressly permitted the duty to warn to be satisfied by a warning to a third party as long as there was 'reasonable assurance that the information will reach those whose safety depends on their having it." *Id.* Similarly, *McLaughlin* found a parallel duty under Pennsylvania law, which had adopted Section 388 of the Restatement (Second) of Torts, including comment n to that Section, which is entitled "Warnings given to third person." 172 F. Supp. 3d at 838. Comment n provides that:

> a supplier's duty to warn is discharged by providing information about the product's dangerous propensities to a third person upon whom it can reasonably rely to communicate the information to the ultimate users of the product or those who may be exposed to its hazardous effects.

Id. Plaintiff has cited to no Michigan law in support of her failure to warn claim.

The Fifth Circuit has also held that a failure to warn claim is not preempted where the plaintiff claims the manufacturer failed to report "serious injuries" caused by the device as required by FDA regulations. *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 768 (5th Cir. 2011). In *Hughes*, the Fifth Circuit distinguished a negligent failure-to-warn claim from the fraud-on-the-FDA theory in *Buckman* because the plaintiffs there did not identify a violation of a state tort duty. *Id*. at 775.

In sum, the Fifth and Ninth Circuits have recognized a failure-to-warn claim arising out of a medical device manufacturer's failure to provide adverse event reports to the FDA, while the Eighth and Eleventh Circuits have held to the contrary. Below, the court sets forth a brief summary of the rationale offered by the courts in support of these divergent conclusions.

First, let us consider the Supreme Court's holding in *Buckman* that plaintiff's fraud claims for alleged misrepresentations to the FDA were impliedly preempted because there was no parallel state tort law which predated the federal enactments in question. 531 U.S. at 353. The Court explored the policy reasons behind its implied preemption doctrine in the case of medical devices and found that the FDA is empowered to punish and deter any fraud against the administration, and allowing state tort

claims to proceed for violations of federal regulations would impede device applicants with administrative hurdles and tort liability which would hinder the premarket approval process. *Id.* at 348-49. But Justices Stevens and Thomas wrote a concurrence opining that if the FDA had determined the manufacturer had committed a fraud on the FDA and the FDA had taken steps to remove the product from the market, parties injured by the fraudulent representations should be allowed to bring state tort law claims. *Id.* at 354-55. Here, there appears to be a factual dispute about whether Bayer's alleged failure to report adverse events to the FDA amounted to a fraud on the FDA. Plaintiff argues that the FDA cited Bayer for failing to report adverse events and for other alleged regulatory violations. (Amended Complaint, ¶ 200(n)-(s)). But Bayer points out that the FDA never removed the Essure device from the market. And it is unclear if the FDA would have required different labeling if Bayer had reported adverse events, or even if it did, whether that revised labeling would have reached Hill's physician.

In deciding the question now before the court, some courts have held that the federal requirement that a drug manufacturer, like Bayer, report adverse events to the FDA parallels state requirements that a manufacturer warn third parties of the dangers of its product because the FDA is required

to make such reports public. *See, e.g., Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 899-900 (M.D. Pa. 2017) (FDA may reasonably be relied upon to disclose information regarding medical device failures to product users, in that the FDA posts such information to a publicly accessible database as a means of warning the public and physicians). To the contrary, courts finding the failure to warn claims to be preempted find that the FDA is not required to make reports of adverse events public. *See Kubicki on behalf of Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 183-85 (D.D.C. 2018) ("it is by no means certain that the FDA would have directed [the manufacturer] to give consumers different or additional information about the [medical device] if the agency had been made aware of other incidents that predated [plaintiff's] [medical] injury;" *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005-1006 (S.D. Ohio 2016) ("[a]dverse event reports are not warnings. Although the FDA "*may* disclose" adverse-event reports, it is not required to do so."); *Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 988-89 (N.D. Ohio 2017) (same).

Having summarized some of the various conflicting positions federal courts outside this Circuit and around the country have taken on the issue of whether a negligent failure-to-warn claim premised on a medical device manufacturer's alleged failure to report adverse events to the FDA is

preempted, the court considers Michigan's negligent failure-to-warn claim in particular to determine if Michigan's common law tort claim is preempted.

In order to state a negligent failure-to-warn claim in a products liability case under Michigan law, a plaintiff must prove that the product was rendered defective by the manufacturer's "failure to warn about dangers regarding the intended uses of the product, as well as foreseeable misuses" of the product. *Gregory v. Cincinnati Inc.*, 450 Mich. 1, 11 (1995). "The Michigan Legislature has codified a product manufacturer's duty to warn end-users about dangers associated with a product's use." *Mitchell v. City of Warren*, 803 F.3d 223, 226 (6th Cir. 2015). The statute provides:

> a product liability action brought against a manufacturer or seller for harm allegedly caused by a failure to provide adequate warnings or instructions, a manufacturer or seller is not liable unless the plaintiff proves that the manufacturer knew or should have known about the risk of harm based on the scientific, technical, or medical information reasonably available at the time the specific unit of the product left the control of the manufacturer.

Mitchell, 803 F.3d at 226–27 (quoting Mich. Comp. Laws § 600.2948(3)). To recover on a failure to warn theory, a plaintiff must prove that: (1) the defendant owed a duty to the plaintiff; (2) the defendant violated that duty; (3) the defendant's breach was a proximate cause of the plaintiff's injuries; and (4) the plaintiff suffered damages. *Warner v. Gen. Motors Corp.*, 137

Mich. App. 340, 348 (1984). Michigan has adopted and follows the learned intermediary doctrine, which holds that a manufacturer has no duty to warn the ultimate consumer if the product is provided for use by a sophisticated consumer. *Brown v. Drake-Willock Int'l, Ltd.*, 209 Mich. App. 136, 148 (1995). This doctrine has been expressly applied in the medical device context, with the result that adequate warnings are owed to physicians and surgeons and not to their patients. Under the learned intermediary rule, the physician is the proper recipient of necessary information or warnings, not plaintiff. *Id.* at 149; s*ee Avendt v. Covidien, Inc.*, 262 F. Supp. 3d 493, 521 (E.D. Mich. 2017). Thus, under Michigan law, any duty in this case would be one owed to Hill's physicians, not Hill herself, and not the FDA.

Under the "narrow gap" requirement, Hill's negligent failure to warn claim is only viable to the extent she seeks to recover for a claimed violation of a traditional state tort law that aligns with a federal requirement. Here, Hill has not alleged any Michigan requirement that a manufacturer report adverse events to the FDA. And based upon her response brief, Plaintiff relies solely on Bayer's alleged failure to warn the FDA of adverse events in support of her failure to warn claim. Accordingly, Hill's negligent misrepresentation and negligent failure-to-warn-FDA claims are impliedly preempted under *Buckman* and must be dismissed. In addition, even if the

claims were not preempted, Hill has failed to plead a causal link between Bayer's alleged regulatory reporting failures and the allegedly insufficient warnings given to her implanting physicians, a deficiency which is fatal to her claims. Bayer argues the FDA-required warnings have not changed since 2011, and Hill has not pled otherwise; thus, Hill has failed to sufficiently plead Counts II and V.

E. Breach of Warranty (Count III) and Negligent Misrepresentation (Count IV)

The court now considers Hill's breach of warranty and negligent misrepresentation claims which are largely duplicative. Bayer argues that Hill's breach of express warranty claims and negligent misrepresentation claims must be dismissed because all of the alleged misrepresentations were statements from the approved labeling, which the FDA determined were not false or misleading.

First, as to her breach of warranty claim, Mich. Comp. Laws § 440.2313 clearly provides that express warranties are limited to statements, descriptions, representations, samples, and models that are "made part of the basis of the bargain." Nevertheless, "[t]he UCC does not require that express warranties be made a part of the written agreement of the parties." *Dow Corning Corp. v. Weather Shield Mfg., Inc.*, 790 F. Supp. 2d 604, 610–11 (E.D. Mich. 2011) (quoting *Price Bros. Co. v. Philadelphia*

Gear Corp., 649 F.2d 416, 422 (6th Cir.1981)). "Under Michigan's version of the Uniform Commercial Code, advertisements and promotional literature can be a part of the basis of the bargain and thus constitute express warranty where they are prepared and furnished by a seller to induce purchase of its products and the buyer relies on the representations." *Id.* (citing *Kraft v. Dr. Leonard's Healthcare Corp.,* 646 F. Supp .2d 882, 890 (E.D. Mich. 2009)).

Here, Hill alleges she relied on certain representations on Bayer's website and in Essure advertisements in determining to have Essure implanted. She alleges the following representations were false: (1) zero pregnancies in clinical trials and pregnancy cannot occur, (Amended Complaint, ¶ 177(a)(b)(h)(o)); (2) physicians must be signed off to perform Essure procedures and must perform at least one Essure procedure every six to eight weeks, *id.* at ¶ 177(c)(i); (3) Essure is "worry free," *id.* at ¶ 177(d)(j)(l); (4) Essure is more effective than tying your tubes or a vasectomy, *id.* at ¶ 177(f); (5) correct placement is performed easily because of design of micro-insert and does not irritate the lining of the uterus, *id.* at 177(m)(s), and the tip of each insert remains visible to your doctor to confirm placement, *id.* at ¶ 177(k);; (6) Essure is a surgery-free permanent birth control, *id.* at 177(g), and eliminates the risks, discomfort,

and recovery time associated with surgical procedures like having your tubes tied, *id.* at ¶ 177(p)(q); (7) Essure forms a long protective barrier against pregnancy, *id.* at ¶ 177(m); (8) Essure inserts are made from trusted materials, the same as used in heart stents, *id.* at ¶ 177(n)(r); and (9) there is no cutting, pain, or scars, *id.* at ¶ 177(t).

Hill's negligent misrepresentation mirrors her breach of warranty claim. In order to state a claim for negligent misrepresentation under Michigan law, a plaintiff must show: (1) justifiable and detrimental reliance on (2) information provided without reasonable care (3) by one who owed a duty of care. *Chesterfield Exch., LLC v. Sportsman's Warehouse, Inc.*, 572 F. Supp. 2d 856, 866 (E.D. Mich. 2008) (citing *Law Offices of Lawrence J. Stockler v. Rose,* 174 Mich. App. 14, 33 (1989)). In support of her negligent misrepresentation claim, Plaintiff alleges the following misrepresentations: (1) qualifying Essure physicians must perform at least one Essure procedure every six to eight weeks (Amended Complaint, ¶ 188(a)); (2) pregnancy cannot occur, *id.* at ¶ 188(b); (3) the viewable portion of the micro-insert serves to verify placement and does not irritate the lining of the uterus, *id.* at ¶ 188(c); (4) there was no cutting, no pain, no scars, *id.* at ¶ 188(d). These are included in the same claims set forth in her breach of warranty claim. All are addressed together below.

Both sides have prepared charts, Bayer to show that the alleged misrepresentations were consistent with FDA approved labeling, and Hill, on the other hand, to show that the statements were in conflict with FDA approved labeling. To the extent Hill relies on FDA-approved language from the FDA-approved statements in the 2016 PIB, she could not have relied on that language in 2011 when she had Essure implanted and thus, the court does not consider that language here. The court considers each alleged misrepresentation below.

1. Zero Pregnancies

Hill seeks to hold Bayer liable for a statement on the Essure website that there were zero pregnancies in clinical trials, and pregnancy cannot occur. (Amended Complaint, ¶ 177(a)(b)(h)(o), ¶ 188(b)). These statements were consistent with FDA-approved statements in the PIB that "In the Essure clinical studies, zero (0) pregnancies were reported in women who had the Essure inserts for up to 5 years." (ECF No. 13-8, PageID.421; 13-9, PageID.449). They are also consistent with the PIB FDA-approved statement that "During the first 3 months following the procedure, your body and the micro-inserts . . . form a tissue barrier . . . so that sperm cannot reach the egg. This prevents you from getting pregnant. You will need to use another form of birth control during this time." (ECF

NO. 13-11, PageID.489). Other courts have concluded that claims based on statements that Essure had "zero pregnancies" in clinical trials were expressly preempted because such statement was approved by the FDA. *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1098 (N.D. Cal. 2016); *McLaughlin v. Bayer Corp.*, No. 14-7315, 2017 WL 697047, at *13 (E.D. Pa. Feb. 21, 2017). Also, Plaintiff does not allege that she became pregnant, thus she could not show detrimental reliance in any event.

2. Physician Sign-Off and Frequent Performance Requirement

Hill also seeks to hold Bayer liable for a statement on its website that physicians must be signed off to perform Essure procedures, and must perform at least one Essure procedure every six to eight weeks. (Amended Complaint at ¶ 177(c)(i), ¶ 188(a)). Bayer argues the sign-off requirement is virtually identical to an FDA-approved statement in the IFUs that, "[t]his device should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instructions for use and in the Physician Training Manual, and have successfully completed the Essure training program. Completion of the Essure training program includes preceptoring in Essure placement until competency is established, which is typically expected to be achieved in 5

cases." (ECF No. 13-6, PageID.367; 13-3, PageID.513). At least two courts have agreed with Bayer and held that the "sign off" physician requirement is consistent with FDA-approved language and is expressly preempted. *Norman v. Bayer Corp.*, No. 16-253, 2016 WL 4007547, at *6 (D. Conn. July 26, 2016); *McLaughlin*, 2017 WL 697047, at *13. This court agrees that the statement regarding physicians being "signed-off" does not go beyond the FDA's approved language and therefore this claim is preempted.

Hill next complains that the statement, "to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks" was misleading. (Amended Complaint, ¶ 177(i); ¶ 188(a)). Bayer responds that Hill has not adequately pled a claim where she does not allege any facts to support a plausible inference that (1) her own doctor was "identified as a qualified Essure physician," who (2) did not perform one placement every 6-8 weeks, and (3) made errors in placing her device, (4) because of his or her infrequent performance of the Essure procedure, which (5) actually caused her injuries. The court agrees and finds that this claim fails for failure to plead plausible facts in support.

3. Worry Free

Hill also seeks to hold Bayer liable for three statements on the Essure website and advertising that the device is "worry free." (Amended Complaint, ¶ 177(d)(j)(l)). One of the statements reads, "Once your doctor confirms that your tubes are blocked, you never have to worry about unplanned pregnancy," *id.* at ¶ 177(d), another that states, "You will never have to worry about unplanned pregnancy again," *id.* at ¶ 177(j), and a third that states simply "worry free." Bayer responds that those statements are consistent with FDA-approved a statement in the PIB that "Essure may be right for you if . . . [y]ou would like to stop worrying about getting pregnant." (ECF No. 13-9 PageID.441). At least two courts that have considered similar claims, have found that the statements that Essure was "worry free" were expressly preempted. *De La Paz*, 159 F. Supp. 3d at 1098; *McLaughlin*, 2017 WL 697047, at *13. This court reaches the same conclusion.

4. Most Effective Birth Control

Hill also argues that Bayer's statement on its website that Essure is more effective than tying your tubes or a vasectomy, *id.* at ¶ 177(f) is a fraudulent misrepresentation. But Bayer has shown that this statement is consistent with FDA information in the IFU which compares Essure with

both tubal ligation and vasectomy procedures and reports a rate of failure for each that is higher than Essure's (ECF No. 13-7, PageID.409), and a PIB statement that "[t]he Essure procedures is 99.83% effective based on five-year clinical study data." (ECF No. 13-9, PageID.442). At least two courts have found that a fraudulent misrepresentation claim based on this statement is expressly preempted. *McLaughlin*, 2017 WL 697047, at *14; *Norman*, 2016 WL 4007547, at *6. This court reaches the same conclusion.

5. Correct Placement and Irritate Lining of the Uterus

Hill also argues that the statement on Bayer's website that correct placement is performed easily because of the design of the micro-insert and that it does not irritate the lining of the uterus, (Amended Complaint, ¶177(m)(s), ¶ 188(c)), are fraudulent misrepresentations. Hill also seeks to hold Bayer liable for statements made in an advertisement that the tip of each insert remains visible to your doctor to confirm placement. *Id.* at ¶ 177(k)(m), ¶ 188(c). Bayer responds that those statements were consistent with FDA-approved statements in that the IFU provides that during the "Essure Micro-Insert Placement Procedure," "[e]xpanded outer coils of the Essure micro-insert trailing into the uterus indicates ideal placement." (ECF No. 13-12, PageID.510). Thus, Hill's claim that

statements regarding the ease of placement of the micro-inserts are fraudulent are preempted. Similarly, the labeling also contained statements that Essure "does not irritate the lining of the uterus," 2008 PIB (ECF No. 13-11, PageID.495). Thus, Hill's assertion that Bayer misrepresented the claim that the device does not irritate the lining of the uterus, (Amended Complaint, ¶ 177(s)), tracks FDA-approved language and is therefore preempted.

6. Surgery Free and Permanent

Hill also argues that the statements that Essure is a surgery-free permanent birth control on its website, (Amended Complaint, ¶177(g)), and the statement in advertising that the device eliminates the risks, discomfort, and recovery time associated with surgical procedures like having your tubes tied, *id.* at ¶ 177(p)(q), is a fraudulent misrepresentation. Bayer, on the other hand, points to FDA-approved statements in the PIB that Essure is "non-surgical" and "does not require surgery or exposure to its potential risks," (ECF No. 13-9, PageID.441), does not require "cutting into the body." (ECF No. 13-11, PageID.491). Other courts have considered the same statements and ruled that they are consistent with, and largely equivalent to FDA-approved statements, and thus, any fraudulent misrepresentation claims based on these statements are expressly

preempted." *See De La Paz*, 159 F. Supp. 3d at 1098; *McLaughlin*, 2017 WL 697047, at * 14. This court reaches the same conclusion.

7. Long Protective Barrier

Hill also seeks to hold Bayer liable for a statement in advertising materials that Essure forms a long protective barrier against pregnancy. (Amended Complaint, ¶ 177(m)). This statement is consistent with FDA-approved statement that, "your body will form tissue around the Essure inserts. This will develop a natural barrier within the fallopian tubes." (ECF No. 13-9, PageID.443). Also, the IFU provides, "[t]he insert expands upon release to conform to and acutely anchor in the tubal lumen." (ECF No. 13-7, PageID.404). Accordingly, the alleged misrepresentation is expressly preempted.

8. Safe, Trusted Material

Hill also argues that Bayer should be held liable for a statement that Essure inserts are made from trusted materials, the same as used in heart stents. (Amended Complaint, ¶ 177(n)(r)). But Bayer has shown those representations are consistent with FDA-approved statements in the PIB that "[t]hese same materials have been used for many years in cardiac stents and other medical devices placed in other parts of the body." (ECF No. 13-9, PageID.448, 13-11, PageID.489).

9. No Cutting, Pain, or Scars

Finally, Hill also argues that Bayer should be held liable for the statement in an advertising booklet that there is no cutting, pain, or scars, (Amended Complaint, ¶ 177(t); ¶ 188(d)). FDA-approved PIB, however, states that there is "[n]o cutting into the body." (ECF No. 13-11, PageID.491). The PIB also states that, "[t]he Essure procedure does not involve cutting into or puncturing your body, and does not cut, crush or burn your fallopian tubes . . . Since there is no incision, you will have no scarring." 2009 PIB (ECF No. 27-1, PageID.794). It further states, "[i]s the procedure painful? Generally, no." (ECF No. 27-1, PageID.797). This language in FDA-approved statements that there is no cutting and no pain or scars is expressly preempted.

V. Conclusion

For the reasons set forth above, Defendants' motion to dismiss (ECF No. 12) is GRANTED in its entirety. Defendants' request for judicial notice is also GRANTED (ECF No. 27).

Dated: September 8, 2020

s/George Caram Steeh
GEORGE CARAM STEEH
UNITED STATES DISTRICT JUDGE